PATENT
ATTORNEY DOCKET NO. 50026/049001

Certificate of Mailing: Date of Deposit: March 7, 2005

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Janet D'Annunzio-Ellis
Printed name of person mailing correspondence

Janet D'Annunzio-Ellis
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Inoue et al.	Art Unit:	To Be Assigned
Serial No.:	10/516,429	Examiner:	To Be Assigned
Filed:	November 30, 2004	Customer No.	21559
Title:	PARAMYXOVIRAL VECTORS ENCODING ANTIBODIES, AND USES THEREOF		

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUBMISSION OF TRANSLATION OF
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Applicants submit herewith the Translation of the International Preliminary Examination Report corresponding to the above-referenced application. Applicants petition for any necessary extensions of time for submission of this document.

In addition, if there are any charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 7 March 2005

James D. DeCamp, Ph.D.
Reg. No. 43,580

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

Translation

PATENT COOPERATION TREATY

PCT/JP2003/007005

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference D3-A0203P	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/007005	International filing date (*day/month/year*) 03 June 2003 (03.06.2003)	Priority date (*day/month/year*) 03 June 2002 (03.06.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/09, 7/00, A61K 35/76, 39/395, 48/00, A61P 19/08, 25/00, 37/06, 43/00, C07K 16/18, 16/28, C12P 21/02		
Applicant DNAVEC RESEARCH INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07 November 2003 (07.11.2003)	15 June 2004 (15.06.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/007005

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP03/07005

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 16-19

because:

☒ the said international application, or the said claims Nos. 16-19 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matters of the above claims relate to methods for treatment of the human body by therapy.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 16-19.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP03/07005

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-15, 20-23	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-15, 20-23	NO
Industrial applicability (IA)	Claims	1-15, 20-23	YES
	Claims		NO

2. Citations and explanations

Documents

Document 1: A Cytoplasmic RNA Vector Derived from Nontransmissible Sendai Virus with Efficient Gene Transfer and Expression, (Li Ho, et al.), J Virol., July 2000, Vol. 74, No. 14, pages 6564-6569

Document 2: Angiogenic Gene Therapy for Experimental Critical Limb Ischemia: Acceleration of Limb Loss by Overexpression of Vascular Endothelial Growth Factor 165 but Not of Fibroblast Growth Factor-2, (I. Masaki, et al.), Circ Res., 17 May, 2002 (17.05.02), Vol. 90, No. 9, pages 966-973

Document 3: Potent Inhibition of Human Immunodeficiency Virus Type 1 in Primary T Cells and Alveolar Macrophages by a Combination Anti-Rev Strategy Delivered in an Adeno-associated Virus Vector, (RT Inouye, et al.), J Virol., May 1997, Vol. 71, No. 5, pages 4071-4078

Document 4: Expression of a Biologically Active Antiviral Antibody Using a Sindbis Virus Vector System, (XH Liang, et al.), Mol Immunol., August-September 1997, Vol. 34, Nos. 12 and 13, pages 907-917

Document 5: High Level Expression of a Human Rabies Virus-neutralizing Monoclonal Antibody by a Rhabdovirus-based Vector, (K. Morimoto, et al.), J Immunol Methods, 1 June, 2001 (01.06.01), Vol. 252, Nos. 1 and 2, pages 199-206

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : V.2

Document 6: Regeneration of Lesioned Corticospinal Tract Fibers in the Adult Rat Induced by a Recombinant, Humanized IN-1 Antibody Fragment, (C. Brosamle, et al.), J Neurosci., 1 November, 2000 (01.11.00), Vol. 20, No. 21, pages 8061-8068
Document 7: CD28-specific Antibody Prevents Graft-versus-host Disease in Mice, (XZ Yu, et al.), J Immunol., 1 May, 2000 (01.05.00), Vol. 164, No. 9, pages 4564-4568

Claims 1-15 and 20-23

Documents 1 and 2 describe that sendai virus is used for vectors for gene therapy, etc. Documents 3-5 describe that polypeptides including an antibody-variable region are expressed by means of virus vectors.

Administering antibodies into living bodies as pharmaceuticals was well known prior to the priority date of the present application. Administering into a living body a virus vector carrying a DNA or an RNA that codes for a protein so that the said protein coded for by the said DNA or RNA can be expressed and function as a pharmaceutical, instead of directly administering the said protein thereinto, was well known to a person skilled in the art prior to the priority date of the present application.

Accordingly, a person skilled in the art could have conceived of the idea of letting the antibody genes described in documents 3-5 express in living bodies by using the vectors described in documents 1 and 2.

A person skilled in the art could have adopted the antibodies to NOGO described in document 6 or those to CD28 described in document 7 as antibodies used in such methods, as required. A person skilled in the art could have used CTLA4 described in document 7 together, as required.

In addition it is not considered that the constitutions of the subject matters of the above claims have a significant effect.

Accordingly, the subject matters of the above-listed claims do not appear to involve an inventive step in view of documents 1-7.